## **A Question of Significance**

TO THE EDITOR: Dr. Henry Bourne's lucid discussion of the University Group Diabetes Program study (Tolbutamide—Therapeutic trials and clinical practice—Medical Staff Conference, University of California, San Francisco, California Medicine 117:45-62, December, 1972) should be very helpful to the clinician in deciding how to treat a diabetic patient. His analysis complements Feinstein's statistical "inquest" and should leave little room for further controversy until a really definitive therapeutic trial can be undertaken.

Dr. Bourne, however, makes one point where I think the emphasis is misplaced. Looking at the comparison between the placebo and insulin variable groups, he takes the small mortality difference observed (10.2 percent in the placebo group and 8.8 percent in the insulin treated patients) as evidence that insulin has had no effect. Surely this puts too much of a burden on the finding of a difference which is not statistically significant. Suppose, for instance, that the true mortality in the placebo population is 12 percent and in the insulin treated population 6 percent; if we draw repeated samples of 204 or 205 from these two groups we would expect to find differences as small as were observed in the study (or smaller) in slightly over 5 percent of our experiments. Consequently, there could very well be a real and important difference in patients treated with insulin. A verdict of statistical non-significance only means that a difference has not been demonstrated —it does not prove that no difference exists.

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## **Meaning of Dysmature**

TO THE EDITOR: My reply to Dr. Szalay's letter (Calif Med 118:41, Jan 1973) is as follows:

Dr. Szalay is quite correct that much confusion does exist not only in regard to terms but also to concepts. Simplification is indicated. The proliferation of terms and categorizations has tended in the past to perpetrate much nonsense and to obscure the fact that these small babies from abnormal pregnancies can be conceptualized more easily as a unit and categorized rather handily as we have tried to do. The stimulus for this classification actually comes from the first report of the British Perinatal Mortality Survey<sup>1</sup> from which the following is quoted: "Dysmature is a term with no agreed on precise definition, which is here used not as a clinical description of an infant but only to apply to those babies that are abnormally small or large by weight for the duration of gestation when this is accurately known." Clifford's "placental dysfunction syndrome"2 refers to babies that are truly postmature—a limited syndrome.

If one identifies a dysmature baby, he then can consider a classification and/or cause—maternal, placental, genetic, metabolic, infectious, etc. The fact that a baby with a 17-18 trisomy for example is small for gestational age is best understood, it seems to me, if we regard him as a dysmature infant due to chromosomal aberration. My bias is clear, that in a confusing area where author after author sought to introduce a new term for the same thing, we would do well to recognize them as fetal growth failures or excesses and then to categorize them according to cause. Otherwise, in addition to Dr. Szalay's "descriptive phrases" we would also be forced to add "fetal malnutrition,"3 "chronic fetal distress," "placental insufficiency syndrome,"5 and "runt."6

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- 3. Scott KE, Usher R: Fetal malnutrition—Its incidence, causes and effects. Am J Obstet Gynecol 94:951, 1966
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  5. Rumbaltz, WL, Edwards, MC, McGoogan, LS: The small full-term infant and placental insufficiency. West J Surg 69:53, 1961
- 6. Scott, JS: Pregnancy as an experimental system for the study of immunological diseases. J Reprod Fert Suppl 3:41, 1968